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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/445,174	04/24/2000	GARRIT-JAN BOUDEWIJN VAN OMMEN	294-78	9590

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EXAMINER
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FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 01/13/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/445,174

Applicant(s)

VAN OMMEN ET AL.

Examiner

Jeffrey Fredman

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 15-18 and 56-71 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 63-71 is/are allowed.
- 6) ☒ Claim(s) 15-18 and 56-61 is/are rejected.
- 7) ☒ Claim(s) 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112 – First paragraph***

1. The rejection of claims 15-55 under 35 U.S.C. 112, first paragraph, is withdrawn in view of the limitation of the claims to deletions which comprise the entirety of exon 13 or exon 22. The amendment to remove the phrase "a major part of" limits the claims to deletions which comprise "exon 13" or "exon 22" and since the claims no longer include subsegments of these exons, the claims are in compliance with the written description requirement.

### ***Claim Rejections - 35 USC § 112***

2. The rejection of claims 15-55 under 35 U.S.C. 112, second paragraph, is withdrawn in view of the amendment.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 15-18 and 56-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Miki et al (Science (1994) 266:66-71).

Miki teaches PCR primers to amplify every exon of BRCA1 including exons 13 and 22 (page 71, footnote 26 states that primers for every exon are available publicly upon request). These primers would inherently function in a diagnostic test to detect deletions, and in particular large deletions, of exons 13 and 22 because the resultant PCR products would differ in size from the PCR products of controls without deletions.

claimed invention from the prior art." It is clear that a structural difference must exist between the claimed invention and the prior art to overcome the rejection and not simply a difference in the intended use. As MPEP 2111.02 also notes "a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone." Here, there is no structural difference between the primers claimed by Applicant and those of Miki and consequently, the only distinction is the intended use, not the product.

### ***Conclusion***

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is 703-308-6568. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jeffrey Fredman  
Primary Examiner  
Art Unit 1637

January 7, 2003

Further, Miki teaches the resultant PCR products (page 71, footnote 26) which PCR products would inherently function as hybridization probes for detection of exons 13 and 22 which PCR products would comprise a sequence complementary to both sides of the deletion. Miki teaches the elements necessary for southern and northern blotting (page 69, figures 3 and 4). The primers of Miki necessarily include nested sets of primer pairs since primers for exon 13 for example, would be nested within the 5' primer of exon 12 and the 3' primer of exon 14. Miki teaches radioactive labeling of the probes (see page 69, figure 5).

***Allowable Subject Matter***

5. Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
6. Claims 63-71 are allowed.
7. The following is a statement of reasons for the indication of allowable subject matter: Claim 62 is drawn to a specific labeled probe where the probe comprises a fusion between ALU-elements in the BRCA1 gene. There is no teaching or suggestion in the Miki reference or the other cited prior art that such a probe exists. This probe is structurally different from the full length BRCA1 gene or its cDNA because it requires the ALU elements to fuse. With regard to method claims 63-71, these claims are drawn to detection of BRCA1 deletions of the entire exon 13 or the entire exon 22. While there is prior art teaching detection of BRCA1 deletions, the prior art does not teach or suggest the deletion of the entire exon within the BRCA1 gene in the genome.

Consequently, the claimed invention drawn to methods of detection of these two novel deletions are novel and unobvious.

### ***Response to Arguments***

8. Applicant's arguments filed December 9, 2002 have been fully considered but they are not persuasive.

Applicant argues that the Miki reference sequences may not be available to all. This statement represents an argument by the attorney which is directly opposed to the statement of the reference. MPEP 716.01(c) makes clear that

"The arguments of counsel cannot take the place of evidence in the record. In re Schulze , 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long - felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant."

Here, the statements regarding inoperability of the prior art must be demonstrated, not simply argued.

Further, under 35 U.S.C. 102(b), public use in the United States is all that is necessary to invoke the statute. Miki's use of the primers in Utah, coupled with the express statement that the sequence information is publicly available, clearly demonstrates a public use.

Applicant then argues the intended use of the primers differentiates the claim from the Miki reference. As MPEP 2111.02 notes "Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the